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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,957	10/30/2003	Reiner L. Gentz	PF402C1D1	7693

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EXAMINER

XIE, XIAOZHEN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,957	GENTZ ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20031030</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The Information Disclosure Statement (IDS) filed 30 October 2003 has been entered. Claims 1-76 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities:

The Application No: 09/853,666 is now patented. The first line of the specification should include updated cross-reference to related applications.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19, 21, 22, 24-32, 34-65, 67-73, 75 and 78-81 of U. S. Patent No: 6,238,888 B1.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, claims 1-19, 21, 22, 24-32, 34-65, 67-73, 75 and 78-81 of U. S. Patent No: 6,238,888 B1 are drawn to a pharmaceutical composition comprising a KGF-2 polypeptide of Ser (69)—Ser (208) (KGF-2Δ33). The KGF-2 formulation of the 6,238,888 B1 patent differs from the pharmaceutical composition of KGF-2 claimed in the instant application in that the instant KGF-2 formulation reciting different ranges of: 1) NaCl (range of about 0.1-150 mM, 0.1-125 mM, or 0-125 mM); 2) a chelating agent or EDTA (range of about 1-10 mM); 3) sucrose (range of about 0-5%); 4) viscosity

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(range of about 0-10,000); 5) a copolymer of Pluronic 127 or Poloxamer 407; and reciting 6) a thickened KGF-2 solution composition comprising a topically effective amount of KGF-2, or a KGF-2 gel formulation comprising a pharmaceutically active amount of KGF-2; whereas the 6,238,888 B1 patent reciting: 1) NaCl (range of about 0.01-150 mM or 0.01-125 mM); 2) a chelating agent or EDTA (range of about 0.1-10 mM); 3) sucrose (range of about 0.01-5%); 4) viscosity (range of about 0.1-10,000); 5) a copolymer of a polyoxypropylene-polyoxyethylene block copolymer having an average molecular weight of 12,600; and reciting 6) a thickened KGF-2 solution composition comprising a KGF-2 polypeptide in a concentration range of about 0.01 ug/ml to about 10 mg/ml, or a KGF-2 gel formulation comprising a KGF-2 polypeptide in a concentration range of about 0.01 ug/ml to about 10 mg/ml. Although the conflicting claims are not identical, they are not patentably distinct from each other because either the instant claims are broader in scope, for example, sucrose concentration and viscosity range, which encompassing the ranges related to the KGF-2 formulation claimed in the 6,238,888 B1 patent, or the instant claims would have been obvious over the claims of the 6,238,888 B1 patent, for example, the ranges of concentrations of NaCl, chelating agent EDTA, and KGF-2 overlap significantly with those recited in these claims. In addition, The portions of the specification in the 6,238,888 B1 patent also support the recited KGF-2 solution composition comprising a topically effective amount of KGF-2, (e.g. a preferred thickened KGF-2 polypeptide solution comprises a product formed by mixing a topically effective amount of a KGF polypeptide, preferably KGF-2Δ33 (column 8, lines 36-51)), and a KGF-2 formulation comprising a pharmaceutically

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active amount of KGF-2, (e.g. a preferred gel formulation comprises a pharmaceutically active amount of KGF-2 polypeptide (column 10, lines 28-37)), which are included in the embodiments of the instant claims. Similarly, The portions of the specification in the 6,238,888 B1 patent support the recited copolymers, e.g. preferred high molecular weight gel forming compounds are polyoxypropylene-polyoxyethylene block copolymers, especially those block copolymers that are designated in the trade as PLURONICS, and preferred block copolymers are Pluronic F127 (average MW: 12,600) (column 9, lines 37-51), which are included in the embodiments of the instant claims. The instant claims cannot be considered patentably distinct over the claims of the 6,238,888 B1 patent when there are specifically recited embodiments that would anticipate the instant claims. Alternatively, the instant claims cannot be considered patentably distinct over the claims of the 6,238,888 B1 patent when there are specifically disclosed embodiments in the 6,238,888 B1 patent that support the claims of that patent and fall within the scope of the instant claims, because it would have been obvious to one of ordinary skill in the art to modify of the KGF-2 formulation recited in the claims of the 6,238,888 B1 patent by selecting specifically disclosed embodiments that support those claims. One ordinary skill in the art would have been motivated to do so because the embodiments are disclosed as being preferred embodiments within the claims of the 6,238,888 B1 patent.

Therefore, claims 1-76 are anticipated by claims 1-19, 21, 22, 24-32, 34-65, 67-73, 75 and 78-81 of the 6,238,888 B1 patent.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6, 33, 56, 75 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 and 33 are indefinite for the recitation of "said KGF-polypeptide" or "said KGF polypeptide". There is insufficient antecedent basis for this limitation in the claims.

Claim 56 is indefinite for the recitation of "a KGF polypeptide" in (1), wherein the preamble states "KGF-2 polypeptide".

Claims 75 and 76 are indefinite for the recitation of "said KGF-2 polypeptide is a N-terminal deletion selected from the group consisting of Ala(63)—Ser(208)" (claim 75), or "said KGF-2 polypeptide is a N-terminal or C-terminal deletion mutant selected from the group consisting of Ala(39)—Ser(208);...Met(1), Thr(36); and Cys(37)—Lys(153)" (claim 75). It is unclear what sequence these mutant are derived from, and what is the sequence of Met(1), Thr(36), for example.

Claim Objections

Claim 22 is objected to because of the following informalities: Claim 22 is identical to claim 2. Appropriate correction is required.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**ELIZABETH KEMMERE
PRIMARY EXAMINER**

Xiaozhen Xie, Ph. D.
March 1, 2006